

REMARKS

The only issues outstanding in the Office Action mailed July 23, 2008, are the rejections under 35 U.S.C. 112. The Examiner is thanked for indicating withdrawal of the prior rejections under 35 U.S.C. §§ 101, 112, 102 and 103, and the doctrine of obviousness-type double patenting. Reconsideration of the remaining outstanding issues is respectfully requested.

Rejections Under 35 U.S.C. 112

Claims 1-4, 6-9 and 11-14 have been rejected under 35 U.S.C. 112, first paragraph. Reconsideration of this rejection is respectfully requested.

It is argued, at page 2 of the Office Action, that the specification, while enabling for salts or stereoisomers of compounds of formula I, does not provide enablement for “solvates” of these compounds. While applicant continue to disagree for the reasons of record, the solvates have been cancelled in order to expedite prosecution. Withdrawal of this rejection is therefore respectfully requested.

Claims 12 and 13 have also been rejected under 35 U.S.C. 112, first paragraph. It is argued that the specification, while enabling for treatment of depression, does not provide enablement for other diseases. Applicants respectfully disagree with this analysis. However, it is noted that the outset that, in order to focus the issues for a potential appeal, the claims have been limited to anxiolytic, anti-depressant, neuroleptic and/or anti-hypertonic effects, and treatment/prevention of migraine or cerebral infarction, such as stroke and ischemia (see new claim 15) and treatment of obsessive compulsive disorder. The revised claims are clearly supported in the present specification at page 11, lines 25-27, page 12, lines 30-32, and page 15, lines 6-8. It is respectfully submitted that these indications are moreover clearly enabled by the specification. At page 4 of the Office Action, the rejection launches immediately into a discussion of the “Wands” factors. However, the courts have made it amply clear that a consideration of these factors is *not* the first step in the enablement analysis. See *In re*

Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). The *Marzocchi* court has stated that the first step in the analysis is whether “objective enablement” is present. Such objective enablement is provided simply by a statement in the specification that the claims are enabled for as broad a scope as is claimed. Such a statement is present in the specification, for example, at page 11, lines 25-27, page 12, lines 30-32 and page 15, lines 6-8, among other places. The *Marzocchi* court then indicated that the burden, where objective enablement has been provided, shifts to the Patent and Trademark Office to provide “reasons or evidence” to doubt the objective enablement. If such reasons or evidence are provided, then the burden shifts back to the Applicant’s to establish that the invention is enabled without undue experimentation. *Marzocchi, supra*. It is not seen that the discussion of the Wands factors at pages 4-6 of the Office Action provide such reasons or evidence. In particular, it appears that a principle concern is the breath of the method claims. However, *Marzocchi* has established beyond doubt that mere breath is insufficient reasons or evidence to doubt enablement:

Turning specifically to the objections noted by the Board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that Applicants, when they included the disputed terms in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by Applicants that all of the ‘considerable number of compounds’ which are included in the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only relevant concern of the patent office under these circumstances should be over the *truth* of any such assertion. The first paragraph of §112 requires nothing more than *objective enablement*. How such a teaching is set forth, either by the use of illustrative examples or by broad term analogy, it is of no importance.

Moreover, even if reasons or evidence to doubt the objective enablement in the specification had been presented, it is clear that, without undue experimentation, one of ordinary skill in the art can easily determine whether a given compound is effective in the method

claimed. One of ordinary skill in the art is armed with the knowledge in the specification that the compounds in the invention are selective serotonin reuptake inhibitors. Since one of ordinary skill in the art also possesses the knowledge that selective serotonin reuptake inhibitors are a class of anti-depressant used in treatment of depression, anxiety disorders and personality disorders, e.g., obsessive compulsive disorder, and also effective against chronic pain, one of ordinary skill in the art would know that the compounds of the invention are effective in the indications claimed herein. Such is moreover evident from the present specification in which an anxiolytic and anti-depressant activity of selective serotonin reuptake inhibitors is discussed, for example, at page 1, noting PCT application WO 99/51575, and by WO 96/16056 disclosing treatment of vascular-related headaches, including migraine with such selective serotonin reuptake inhibitors. Moreover, WO 99/51575 discloses an anxiolytic and anti-depressant activity. See also *Soomro GM, Altman D, Rajagopal S, Oakley-Browne M, see <http://www.cochrane.org/reviews/en/ab001765.html>*, disclosing the use of selective serotonin reuptake inhibitors in the treatment of obsessive compulsive disorder, and *PIRES J. G.P.; BONIKOVSKI V.; FUTORO-NETO H.A.; Brazilian Journal of Medical and Biological, 2005, Vol. 38, n 12, pp. 1867-1872* disclosing the effects of selective serotonin reuptake inhibitors on neuroleptic induced catalepsy in mice.

In addition, the Office Action admits that one of ordinary skill can easily screen the compounds for the activity which indicates utility in the claimed methods, see the Office Action at page 5. It is thus clear that one of ordinary skill can, with only routine experimentation assess activity of a given compound and then employ that compound in routine treatment methods. Nothing more than that is needed for enablement. It is thus respectfully submitted that the claims are clearly enabled, and withdrawal of the rejection in this regard is respectfully requested.

Claims 11-12 have also been rejected under 35 U.S.C. 112, second paragraph. Reconsideration of this rejection is respectfully requested.

Claim 11 has been cancelled in order to expedite prosecution, and thus this portion of the

rejection is moot. The objection to claim 12 apparently regards the “such as” phrase, which has been clarified. Accordingly, the submitted claim is definite, and withdrawal of this rejection is also respectfully requested.

The claims in the application are all submitted to be in condition for allowance, however, if the Examiner has any questions or comments, he or she is cordially invited to telephone the undersigned at the telephone number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Harry B. Shubin/

Harry B. Shubin, Reg. No. 32,004
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-3099

Date: December 23, 2008